K053298

MAY - 9

ALPHASPHERE ORBITAL IMPLANT
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Hydron Pty Limited (t/a) CooperVision Surgical Lions Eye Institute Building 2 Verdun Street Nedlands WA 6009 Australia
TRADE NAME:	AlphaSphere Orbital Implant
COMMON NAME:	Orbital Implant
CLASSIFICATION NAME:	Eye Sphere Implant
DEVICE CLASSIFICATION:	Class II, 21 CFR §886.3320
PRODUCT CODE	HPZ
PREDICATE DEVICE:	The AlphaSpere Orbital Implant is substantially equivalent in intended use and mechanism of action to the Porex Surgical's Medpor® Quad Motility Implant (K010902) and to Integrated Orbital Implants' Bio Eye II (K003338). The AlphaSphere is also substantially equivalent to the AlphaCor Artificial Cornea, (K013756) in material formulation and mechanism of action for device integration.

SUBSTANTIALLY EQUIVALENT TO:

The AlphaSphere Orbital Implant is substantially equivalent in intended use and mechanism of action to the Porex Surgical's Medpor® Quad Motility Implant (K010902) and to Integrated Orbital Implants' Bio Eye II (K003338). The AlphaSphere is also substantially equivalent to the AlphaCor Artificial Cornea, (K013756) in material formulation and mechanism of action for device integration.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The AlphaSphere Orbital Implant is aspherical orbital volume replacement prosthesis with a posterior gel hemisphere resistant to tissue ingrowth and an anterior hemisphere with a spongy outer surface designed to encourage tissue attachment.

INDICATION FOR USE:
The AlphaSphere Orbital Implant is intended to replace orbital volume after loss of an eye through enucleation or evisceration. The device is indicated in any situation where silicone, acrylic, polyethylene, coral, glass, or other traditional orbital implants are used.

TECHNICAL CHARACTERISTICS:
The implant is made entirely of a flexible hydrogel, poly (2-hydroxyethyl methacrylate), (PHEMA). The physical differences between the gel and spongy portions of the implant are created by varying the conditions during the hydrogel polymerization process. The transition between the two hydrogel regions is reinforced with a biocompatible synthetic mesh (MERSILENE) beneath the device surface to improve mechanical strength for the passage of sutures.

PERFORMANCE DATA:
The determination of substantial equivalence, in addition to aspects of design, function and indications, is based on performance data indicating that the AlphaSphere Orbital Implant is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

Safety: The constituents of AlphaSphere, PHEMA and Mersilene, have a history of use as implanted devices, and are of known biocompatibility. The device is provided sterile and accurately sized for optimal outcome. Evidence of the biocompatibility of the PHEMA material has been established through a number of published peer-reviewed studies, which additionally demonstrate that the material, in its macroporous form, allows biointegration from surrounding tissues. Chirila TV et al (Biomaterials 1993;14: 26-38) demonstrated cellular invasion of PHEMA sponges in the rabbit model. A prototype artificial cornea, now marketed as AlphaCor, was found biocompatible in the rabbit cornea, where biointegration with its peripheral macroporous skirt was confirmed (Crawford GJ et al. J Refract Surg 1996;12:525-529; Hicks CR et al. Br J Ophthalmol 1998; 82:18-25; Vijayasekaran S et al. Cornea 1997;16:352-359), even in inflamed post-alkali burn tissues (Hicks CR et al. Cornea 1998; 17:301-308).

Performance: Integrity of the device *in situ* is assured through the strength of the interpenetrating polymer network (IPN) through which the sponge and gel portions of AlphaSphere are unified (Chirila TV et al. J Biomed Mater Res 1994; 28:745-753). The presence of the Mersilene mesh in the region of the IPN is not to strengthen the IPN itself, which is very strong, but to provide a firm anchorage for bites of extraocular muscle suture, allowing the surgeon to exert traction as necessary to draw the muscle against the device surface without risking tearing of the device sponge surface. *In vitro* studies with AlphaSphere, using a Sintech mechanical tester, demonstrate adequate mechanical strength.

Effectiveness: Evidence of satisfactory clinical handling, retention and performance is available from published animal studies performed during development of the AlphaSphere Orbital Implant. It was demonstrated that the device can be implanted, without prior tissue or mesh coverage, and without drilling or soaking or other measures often recommended for alternative types of orbital implant, directly into the socket after enucleation, and extraocular muscles directly attached by passing sutures through the sponge region of the device (Hicks CR et al. Ophthal Plast Reconstr Surg 1999;15:326-332). Information demonstrating substantial equivalence in effectiveness is summarized from published studies of the AlphaSphere and predicate MEDPOR devices in rabbits.

	AlphaSphere	**MEDPOR**
Study authors	Hicks CR, Morris IT, Vijayasekaran S, et al.	Jordan, D. R., Brownstein, S., Dorey, M.,et al.
Reference	Br J Ophthalmol 1999; 83: 616-21	Ophthalmic Plast Reconstr Surg 2004; 20:136-43
Methods	Following enucleation, 8 rabbits received PHEMA implants to which the muscles were directly sutured, and underwent gadolinium enhanced magnetic resonance imaging (MRI) from 3 to 52 weeks. Following sacrifice, the implants were removed, cut in a plane corresponding to the scan, and processed for light and electron microscopy evaluation of the histopathology.	10 rabbits underwent enucleation followed by placement of porous polyethylene implant. In 5 animals, the implant was encased in Vicryl mesh; in the other 5, it was left unwrapped. The implants were moistened in saline before placement. Implant vascularization was evaluated by histopathology at 4, 8, 12, 16, and 24 weeks.
Results	All 8 rabbits retained their implant to the end of the study period without complications. The scans demonstrated muscle attachment to the anterior half of the implant, and enhancement was seen. Histology confirmed muscle attachment, and cellular and vascular ingrowth. Over time, a transformation from reactive inflammatory to relatively non-vascular scar tissue was seen within the implant.	One rabbit had a retrobulbar hemorrhage after surgery and was euthanized. All the other rabbits tolerated the implant well, and there were no complications. On histopathologic examination, fibrovascularization increased over time. One implant was completely vascularized at 12 weeks. The implant harvested at 24 weeks showed only partial vascularization.
Conclusion	Muscle attachment and fibrovascular ingrowth into the anterior hemisphere are confirmed. There is initial inflammation and vascularization, developing into quiescent fibroblastic tissue.	The porous polyethylene implant was well tolerated without complication. Complete fibrovascularization was first seen at 12 weeks.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the AlphaSphere Orbital Implant are similar to the predicate orbital implants cited in this application. The safety of the materials used for the manufacture of AlphaSphere has previously been demonstrated. Testing demonstrates that the AlphaSphere Orbital Implant is functionally equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

MAY - 9 2006

Re: K053298
Trade/Device Name: AlphaSphere Orbital Implant
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye sphere implant
Regulatory Class: Class II
Product Code: HPZ
Dated: April 3, 2006
Received: April 6, 2006

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053298

Device Name: AlphaSphere Orbital Implant

Indications for Use:

The AlphaSphere Orbital Implant is intended to replace orbital volume after loss of an eye through enucleation or evisceration, including secondary implantation after removal of an existing, unsatisfactory, orbital implant. The device is indicated in any situation where silicone, acrylic, polyethylene, coral, glass, or other traditional orbital implants are used.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K053298